

#4/IDS

PATENT  
Docket No. P-8383  
jc525 U.S. PTO  
09/301842  
04/29/99

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Brian FERNANDES et al. ) Group Art Unit: Unknown  
Serial No.: Unknown ) Examiner: Unknown  
Filed: Herewith )  
For: IMPLANTABLE MEDICAL DEVICE WITH ENHANCED  
BIOCOMPATIBILITY AND BIOSTABILITY

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
ATTN: Box Patent Application  
Washington D.C. 20231

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

The Examiner is further requested to note that the attached 1449 form(s) list documents that were previously cited by or submitted to the PTO in a prior application (U.S. Serial No. 09/063,227 filed April 20, 1998) that was relied upon for an earlier filing date under 35 U.S.C. §120. As stated in the MPEP §609, “[ t]he examiner will consider information cited or submitted to the Office and considered by the Office in a prior application relied on under 35 U.S.C. §120” without the need for applicant to provide copies in the pending application.

Copies of the documents that were not cited by or submitted to the Office in the prior application are enclosed herewith. These include:

**Information Disclosure Statement**

Page 2 of 3

Serial No: Unassigned

Filed: Herewith

Title: IMPLANTABLE MEDICAL DEVICE WITH ENHANCED BIOCOMPATIBILITY AND BIOSTABILITY

- AD.
- Brais et al., "Acceleration of Tissue Ingrowth on Materials Implanted in the Heart", The Annals of Thoracic Surgery, 21, 221-229 (1976).
- Cenni et al., "Platelet and coagulation factor variations induced *in vitro* by polyethylene terephthalate (Dacron®) coated with pyrolytic carbon", Biomaterials, 16, 973-976 (1995).
- French et al., "Rifampicin Antibiotic Impregnation of the St. Jude Medical Mechanical Valve Sewing Ring: A Weapon Against Endocarditis", The Journal of Thoracic and Cardiovascular Surgery, 112, 248-252 (1996).
- Kadoba et al., "Experimental comparison of albumin-sealed and gelatin-sealed knitted Dacron conduits", The Journal of Thoracic and Cardiovascular Surgery, 103, 1059-1067 (1992).
- Karck et al., "Pretreatment of prosthetic valve sewing-ring with the antibiotic/fibrin sealant compound as prophylactic tool against prosthetic valve endocarditis", Eur. J. Cardio-thorac Surg., 4, 142-146 (1990).
- Leake et al., "Comparative Study of the thromboresistance of Dacron® combined with various polyurethanes", Biomaterials, 10, 441-444 (1989).
- Miller et al., "Generation of IL1-like activity in response to biomedical polymer implants: A comparison of *in vitro* and *in vivo* methods", J. of Biomed. Mat. Res., 23, 1007-1026 (1989).
- Onuki et al., "Accelerated Endothelialization Model for the Study of Dacron Graft Healing", Annals of Vascular Surgery, 11, 141-148 (1997).
- Orszulak et al., "The risk of stroke in the early postoperative period following mitral valve replacement", European Journal of Cardiothoracic Surgery, 9, 615-620 (1995).
- Perier et al., "Comparison of thromboembolic and anticoagulant-related complications after aortic valve replacement using Starr Edwards, Bjork-Shiley and porcine valve prostheses", Bodnar E, Yacoub M (eds). Biologic and Bioprosthetic Valves: York Medical Books, 511-520 (1986).
- Rubin et al., "Preincubation of Dacron grafts with recombinant tissue factor pathway inhibitor decreases their thrombogenicity *in vivo*", J. Vasc. Surg., 24, 865-870 (1996).
- Schwartz et al., "Local anticoagulation of prosthetic heart valves", Circulation, 43 (Suppl. III), 85-89 (1973).
- Shankar et al., "Chapter 5: Inflammation and Biomaterials", Implantation Biology, Host Response and Biomedical Devices, (eds) Ralph S. Greco, CRC Press, Inc., Boca Raton, FL 67-80 (1994).
- Takahashi, "Adsorption of Basic Fibroblast Growth Factor onto Dacron Vascular Prosthesis and Its Biological Efficacy", Artif Organs, 21, 1041-1046 (1997).
- Tweden et al., "Accelerated Healing of Cardiovascular Textiles Promoted by an RGD Peptide", J. Heart Valve Dis, 4 (Suppl. I), S90-97 (1995).

**Information Disclosure Statement**

Page 3 of 3

Serial No: Unassigned

Filed: Herewith

Title: IMPLANTABLE MEDICAL DEVICE WITH ENHANCED BIOCOMPATIBILITY AND BIOSTABILITY

---

af  
A.L.  
Van Der Lei et al., "Improved healing of small-caliber polytetrafluoroethylene prostheses by induction of a clot layer: a review of experimental studies in rats", International Angiology 10, 202-208 (1991).

Wilkerson et al., "Biomaterials Used in Peripheral Vascular Surgery" (eds) Ralph S. Greco, CRC Press Inc., Implantation Biology: The Host Responses and Biomedical Devices, 179-190 (1994).

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number with any questions regarding this matter.

Respectfully submitted,

By their Representatives,

MEDTRONIC, INC.  
7000 Central Avenue Northeast  
Minneapolis, Minnesota 55432

Date

4-29-99

By:

Thomas F. Woods

Thomas F. Woods

Reg. No. 36,726

Direct Dial (612/514-3652)